December 2004

Massachusetts Board of Registration in Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Boston, MA 02114
www.state.ma.us/reg/boards/ph/default.htm

1. New Board Member Appointments:

The month of July brought a record number of new members to the Massachusetts Board of Registration in Pharmacy with the appointment of the following members:

Donald D. Accetta, MD, Allergy and Asthma Care, PC; Joel R. Berman, RPh, director of pharmacy operations, Stop & Shop Pharmacy; George A. Cayer, RPh, director of pharmacy operations, PharMerica; William A. Gouveia, RPh, MS, director of pharmacy, Tufts-New England Medical Center; and Sophia Pasedis, RPh, PharmD, director of pharmacy, Mass Eye & Ear Infirmary.

2. New Board Positions Announcement

1. Leo A. McKenna III, RPh, PharmD, was recently hired as the Board's full-time continuing quality improvement coordinator. Leo's position will be to assist on a medication error triage committee, develop educational outreach programs, serve as a resource to the regulated community in process improvement efforts, and to survey, where appropriate, health care systems where pharmaceutical care services are being provided.
2. Samuel J. Penta, RPh, was recently hired as an investigator for the Board. Sam will respond to consumer complaints and investigate complaints of drug diversion, substance abuse, and other violations of Board of Pharmacy Regulations. In addition, Sam will conduct assigned inspections of community pharmacies, nuclear pharmacies, wholesale distributors, and other licensed premises.

3. Board and Department of Public Health – Drug Control Program Adopt New Joint Policy 2005-1

"Continuation of drug therapy upon discontinuance of a practitioner's practice."

When a pharmacist becomes aware that a practitioner, or other person authorized to prescribe in accordance with M. G. L. c. 94C, has ceased to practice for any reason and that the practitioner-patient relationship has ended, existing drug therapy may still need to be continued. Therefore, a pharmacist may, pursuant to a prescription previously issued by that practitioner or other authorized prescriber and in the exercise of good professional judgment, dispense remaining refills of a prescription up to a maximum ninety day supply, to enable the patient to establish a relationship with another practitioner. Refills authorized pursuant to this policy may not be dispensed in quantities greater than a thirty day supply in a single filling, except where patient insurance coverage requires dispensing of a sixty or ninety day supply. (adopted October 12, 2004)

4. From the President's Desk

The role of pharmacy technicians has evolved into becoming an integral element of safety and success in the prescription-filling process. In 2002, the Massachusetts Board began the process of registering pharmacy technicians as an opportunity to allow the expansion of their role to improve the practice of pharmacy and enhance public safety.

At this time, all pharmacy personnel acting in the capacity of a pharmacy technician must be registered with the Board. Newly hired technicians are considered "technicians in training" for the first 500 hours of employment, but must register with the Board before they achieve 1,000 hours of employment. The registration process allows the Board to verify their background, experience, training and skills evaluation.

The Board does not require but certainly encourages all technicians to become nationally certified. The current nationally recognized certifying body is the Pharmacy Technician Certification Board (PTCB). Pharmacies who employ PTCB-certified technicians could increase the number of

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New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the counter (OTC) medications that contain levels of calcium, magnesium, sodium, or potassium that might be harmful to persons with certain underlying medical conditions. The final rule was effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with certain medical conditions such as heart disease, hypertension, kidney disease, kidney stones, or other medical conditions could worsen their condition upon consumption of these products. For example, OTC use of medications containing potassium may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the exact amount of a particular ingredient in each dose if they contain:

- 5 mg or more of sodium in a single dose,
- 20 mg or more of calcium in a single dose,
- 8 mg or more of magnesium in a single dose, or
- 5 mg or more of potassium in a single dose.

The rules also require warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult their physician before using oral products that contain maximum daily doses of:

- more than 140 mg sodium,
- more than 3.2 grams calcium,
- more than 600 mg magnesium, or
- more than 975 mg potassium.

Currently the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes. Detailed information on the rulings can be found in the Federal Register at www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm and www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm.

FDA Requests Antidepressant Manufacturers to Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory that cautions physicians, their patients, and families and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports, but it is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to change the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlaxafine (Effexor®), and sertraline (Zoloft®). It should be noted that Prozac is the only drug approved for use in children with major depressive disorder. Prozac, Zoloft, and Luvox are approved for pediatric patients with obsessive-compulsive disorder.

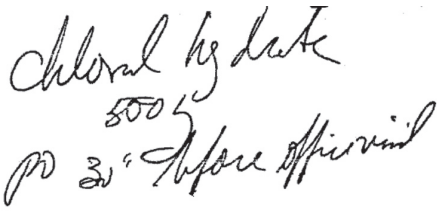
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Further information can be found on CDER's Web site: www.fda.gov/cder/drug/antidepressants/default.htm.

Let Past Experience with Chloral Hydrate Syrup Guide its Safe Use

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Chloral hydrate can be used safely to sedate pediatric patients for diagnostic procedures such as endoscopic procedures, CT scans, or MRIs. However, in several error reports over the years we have seen the sad stories of fatalities that have occurred after excessive doses of the drug were dispensed in error. Typically, deaths have occurred in cases where the order was not clear or when untrained individuals, both staff and parents, were involved without adequate supervision or the knowledge that they were administering an overdose. In some cases, to save time, chloral hydrate has been prescribed for use at home prior to travel to the practice site. In one instance, a 500 mg/5 mL concentration was dispensed instead of 250 mg/5 mL, which also is available. Unfortunately, the dose was prescribed by volume (teaspoonful), which made detection of the twofold overdose impossible. In another incidence, 120 mL of syrup was incorrectly dispensed instead of the prescribed 12 mL. The label instructed the mother to give her child the entire bottle, which she did. Without trained personnel and emergency equipment present to treat these accidental overdoses, the children in both cases died.

Recently the tragedy happened again. A prescription was written for a 17-month-old child; the pharmacist read the directions as "30 cc before office visit" and instructed the mother to give her child that amount. In truth, the physician wanted the child to receive 500 mg 30 *minutes* before the office visit. The double hash-mark symbol ("), which the physician intended to mean minutes, was misread as cc. Actually, a double hash mark stands for seconds; a single hash mark (') is used for minutes. Neither symbol should be used in medicine, however, because not everyone understands their meaning.



Errors also happen in diagnostic areas where technical support personnel often administer oral conscious sedation even though they are not properly trained. In some cases, an ambiguous physician order such as "give chloral hydrate 5 cc prn sedation" or ". . . prn agitation," rather than a specific milligram amount and maximum dose, has led to events where multiple doses of chloral hydrate were dispensed from the supply available to personnel. By the time the child fell asleep, the amount administered was a massive overdose leading to respiratory arrest.

Please consider reviewing your process for dispensing oral liquids used for conscious sedation in children, whether to a medical facility or to a family member. We suggest that the following precautions, in addition to package insert recommendations, be employed. Advise physicians that the drug should not be prescribed by volume (eg, "5 mL," "one teaspoonful," etc). There are two available concentrations of this drug. Instead, the specific milligram dose should be expressed. The prescription should state that it is for pre-procedure sedation. In hospital situations or when pharmacies dispense to health care facilities, prescriptions are best dispensed for each patient in labeled, unit-dose, oral syringes; providing the product in bulk packages as floor stock is less safe. We believe it is safest for pharmacists to *not* dispense prescriptions for patient use in the home when it is for pre-procedure sedation. Should the caregiver receive such a prescription, he or she should be advised that they are safest for the dose to be administered where the procedure will be performed. Official labeling for Versed® Syrup, another drug used for conscious sedation in children, notes that the syrup is intended for use only in monitored settings, never the home. Also, as noted in the product's boxed warning, only health care professionals trained in conscious sedation procedures and authorized to administer conscious sedation drugs should do so. Careful monitoring by direct visual observation is necessary and age-/size- appropriate resuscitation equipment must be readily available. The American Academy of Pediatrics agrees; the Academy's current "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" (*Pediatrics* 2002; 110:836-838) recommend that children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel. These medications should be administered by, or in the presence of, individuals skilled in airway management and cardiopulmonary resuscitation and administered in a health care facility where appropriate monitoring, including continuous pulse oximetry, can be instituted.

One final argument for administering children's sedation on site is to ensure proper timing in case of unpredictable schedule delays.

NABP Releases Updated NAPLEX Blueprint

NABP has released the updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®). The blueprint is available for viewing on NABP's Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers in the entire examination blueprint instead of focusing it within a single competency area as with the current NAPLEX. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

The updated blueprint and competency statements require a new passing standard. However, the NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate's ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX. The new passing standard will go into effect along with the updated blueprint in spring 2005.

For more information about the NAPLEX, contact the Customer Service Department by calling 847/391-4406 or visit the Association's Web site at www.nabp.net.

December 2004 FPGEE Date and Location Announced

On December 4, 2004, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Mateo, CA. Candidates who have been accepted to sit for the December 4, 2004 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE™, a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP's Web site at www.nabp.net.

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support staff up to a 4 to 1 ratio, provided it meets with the approval of the pharmacist supervising the technician. PTCB-certified technicians can also take on additional responsibilities in the pharmacy such as, under certain circumstances, accepting oral prescription orders and assisting with the handling of Schedule II controlled substances.

Pharmacy technicians are important to the profession of pharmacy. With the expanded roles and responsibilities technicians now have, pharmacists should have a greater opportunity to provide counseling, intervention, and other pharmaceutical care services to their patients.

Please refer to Board Regulations at 247 CMR § 8.02 for more details.

5. Joint Guideline on Pharmacist Administration of Influenza Vaccine Minimum Requirements (replaces Policy 2004-01)

The DPH recently lifted the pilot status of the pharmacist influenza vaccine program. Regulations of the DPH – Drug Control Program permit pharmacists, **with appropriate training**, to administer influenza vaccine to individuals 18 years of age and over. Further information regarding administration requirements may be viewed at www.mass.gov/reg/boards/ph (Rules & Regulations – "Board Policies").

However, pharmacists should be mindful that on October 13, 2004, the Massachusetts Commissioner of DPH (Christine Ferguson) issued an order establishing the rules and priorities for the distribution and use of the vaccine. The order as well as the latest information about the influenza vaccine situation is posted on DPH's Web site at www.mass.gov/dph.

6. Board Proposes Regulations to Improve Patient Outcomes

On November 9, 2004, the Board held a public hearing on **proposed** amendments to its regulations and added a new section requiring all pharmacies to establish a Continuous Quality Improvement Program.

*15.02: Continuous Quality Improvement Program

(1) Continuous Quality Improvement Program Requirements. Each pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing and preventing Quality-Related Events (QREs). At a minimum, a CQI program shall include provisions to:

(a) designate an individual or individuals responsible for monitoring CQI Program compliance with the requirements of 247 CMR 15.00;

(b) identify and document QREs;

(c) minimize impact of QREs on patients;

(d) analyze data collected in response to QREs to assess causes and any contributing factors;

(e) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and

(f) provide ongoing professional education at least annually in the area of CQI to pharmacy personnel.

15.03: Quality Related Event Discovery, Notification and Documentation.

(1) QRE Discovery and Notification. All pharmacy personnel shall be trained to bring any QRE to the attention of the pharmacist on duty or the pharmacist Manager of Record immediately upon discovery. The pharmacist who has discovered or been informed of a QRE shall immediately provide:

(a) notification to the patient or patient's representative, the prescriber (if indicated in the professional judgment of the pharmacist) and other members of the healthcare team;

(b) directions for correcting the error; and

(c) instructions for minimizing the negative impact on the patient.

(2) QRE Documentation.

(a) A QRE shall be initially documented by the pharmacist who has discovered or been informed of the QRE on the same day the QRE is discovered by or described to the pharmacist.

(b) QRE documentation shall include a description of the event that is sufficient to permit categorization and analysis of the event. QRE documentation shall include:

1. the date when the pharmacist discovered or received notification of the QRE and the name of the person who notified the pharmacy;
2. the names and titles of the persons recording the QRE information and performing the QRE analysis;
3. a description of the QRE reviewed; and
4. documentation of the contact with the patient, or patient's representative, and prescribing practitioner (if indicated in the professional judgment of the pharmacist), and other members of the healthcare team.

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(3) QRE Analysis and Response.

(a) QRE Analysis. The investigative and other pertinent data collected in response to QREs shall be analyzed, individually and collectively, to assess the cause and any contributing factors such as system or process failures. The QRE analysis and assessment shall include:

1. a consideration of the effects on quality assurance related to workflow processes, technological support, personnel training and staffing levels;
2. any recommended remedial changes to pharmacy policies, procedures, systems, or processes; and
3. the development of indicators that identify means against which a pharmacy's program intends to measure its standards over a designated period of time.

(b) Response. Each pharmacy shall inform pharmacy personnel of changes to pharmacy policies, procedures, systems, or processes resulting from recommendations generated by the CQI Program.

15.04: Records

(1) Each pharmacy shall maintain a written copy of its CQI Program description on the pharmacy premises. The CQI Program description shall be readily available to all pharmacy personnel.

(2) Each pharmacy shall maintain a record of all QREs for a minimum period of two years from the date of the QRE report.

(3) QRE records shall be maintained in an orderly manner and filed by date.

(4) QRE records may be stored at a site other than the pharmacy where the QRE occurred.

*As presented for public hearing on November 9, 2004. Following the hearing, revisions could take place; please check the Board's Web site.

7. Reminder to All Pharmacies Employing Interns

All pharmacy interns are required to be registered by the Board prior to commencing internship. The Board issues to pharmacy interns a registration certificate, which should be shown to the preceptor prior to the preceptor agreeing to supervise them.

8. Pharmacist License Renewals and Continuing Education Reminder

License renewal applications were recently mailed October 22, 2004 – please consider the consequences of signing a renewal under the pains and penalties of perjury **only** after you have physically verified that all your continuing education units are in compliance with Board regulations at 247 CMR § 4.00 et seq.

Before signing, ***please*** conduct a thorough review of 2003 and 2004 continuing education (CE) certificates of completion to ensure full compliance with Board regulations set forth at 247 CMR, §4.03 (www.state.mass.gov/dpl/boards/ph/cmr.htm).

Each calendar year a pharmacist shall complete a minimum of 15 contact hours of CE, of which at least two contact hours shall be in the area of pharmacy law, and not more than 10 contact hours shall be acquired through home study and or other mediated instruction. You are reminded that CE programs must be approved by the Accreditation Council for Pharmacy Education, or a state board of pharmacy, or recognized as Category I Continuing Medical Education by the American Medical Association. The Board recommends that pharmacists participate in CE programs directly related to their practice setting to ensure continued competence in their respective areas of specialization.

Promptly return the completed and signed application renewal and required fee of $75 made payable to the "Commonwealth of Massachusetts" to the Board in the envelope provided. If you do not receive your renewal application and/or have questions related to CE requirements, please contact the Board at 617/727-9953. A $57 late filing fee must accompany any renewal application postmarked after December 31, 2004. Please do not send in your certificates of CE completion along with the renewal application.

Pharmacists should be mindful that a Board waiver provision exists wherein licensees unable to complete requisite CE due to extenuating circumstances and/or physical disability may submit a detailed statement to the Board, signed under penalties of perjury, for consideration related to renewal status. Please be advised that the Board will conduct a random CE audit to assess compliance during the first quarter of 2005.

For more information regarding CE, please review related policy references available on the Board's Web site at www.mass.gov/reg/boards/ph (Rules & Regulations – "Board Policies"): Policy 98-002 regarding CE Audits and Compliance, Policy 98-004 concerning Non-traditional PharmD Programs, and Policy 98-006 addressing Canadian Council on Continuing Pharmaceutical Education and Policy 2000-05 related to Board-approved CE programs.

Please consider providing feedback to the Board about your comments/suggestions about this and future *Newsletters*. Remember, this *Newsletter* is for you, so feel free to send recommendations for future *Newsletters* by e-mail to: charles.young@state.ma.us or james.d.coffey@state.ma.us.

Thank you.

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Happy Holidays

The members and staff of the Massachusetts Board of Registration in Pharmacy wish you a happy and safe holiday season.

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